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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,528	10/26/2000	Masatoshi Takeda	P19743	6685

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EXAMINER
SHUKLA, RAM R

ART UNIT	PAPER NUMBER
1632	24

DATE MAILED: 07/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/581,528	Applicant(s) TAKEDA ET AL	
	Examiner Ram Shukla	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-50* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
4) ☐ Interview Summary (PTO-413) Paper No(s) _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

DETAILED ACTION

1. Claims 1-50 are pending in the instant application.

2. **Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Specifically the application fails to comply with CFR 1.821(d), which states:

> (d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing " in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

In the instant case, while the applicants have submitted CRF and a sequence listing which has been entered in the specification, applicants have not identified sequences in the claims and/or specification with sequence identifiers. For example, claims 3 and 4 recite a particular residue in a sequence, however, claims do not recite a SEQ ID NO. Accordingly, an efficient and proper search of the claimed subject matter will not be possible. Likewise, applicants have recited sequences in claims, such as claim 29. Again, applicants have not identified such sequences with SEQ ID Nos.

For compliance with sequence rules, it is necessary to include the sequence in the "Sequence Listing" and identify them with SEQ ID NO. In general, any sequence that is disclosed and/or claimed as a sequence, i.e., as a string of particular bases or amino acids, and that otherwise meets the criteria of 37 CFR 1.821(a), must be set forth in the "Sequence Listing." (see MPEP 2422.03).

For the response to this office action to be complete, Applicants are required identify each sequence in the specification and in the claims with a SEQ ID NO.

Applicants are also required to provide SEQ ID NO in claims that recite a particular amino acid or nucleotide residue of a particular nucleic acid or protein.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 5-9, 12-17, 33, 36-42, drawn to a non-human gene-mutated animal with a mutant presenelin-1 gene.

Group II, claim(s) 3 and 4, drawn to a non-human gene-mutated animal with a mutant presenelin-1 gene, wherein a particular amino acid has been substituted with another amino acid in the presenilin-1 gene.

Group III, claim(s) 10, drawn to a non-human gene-mutated animal with a mutant presenelin-2 gene, wherein an amino acid at position 141 and / or 436 is substituted.

Group IV, claim(s) 11, drawn to a non-human gene-mutated animal with a mutant presenelin-2 gene, wherein an amino acid at position N141I and / or M239V is substituted.

Group V, claim(s) 18, drawn to a non-human gene-mutated animal with a mutant presenelin-1 gene and a marker protein.

Group VI, claim(s) 19, 20, 25 and 26, drawn to a plasmid comprising a DNA of a mutant presenilin-1 gene.

Group VII, claim(s) 21, drawn to a chromosomal DNA containing exon 8 of a mutant presenilin-1 gene.

Group VIII, claim(s) 22-23, drawn to a plasmid comprising a chromosomal DNA or cDNA encoding mutant presenilin-1 gene and a Sau 3AI site.

Group IX, claim(s) 24, drawn to a plasmid comprising a certain DNA.

Group X, claim(s) 27-28, drawn to a plasmid comprising presenilin-1 encoding sequences, a neomycin expression unit flanked by loxPs.

Group XI, claim(s) 29, 31, and 32, drawn to an embryo comprising a plasmid comprising a certain DNA.

Group XII, claim(s) 30, drawn to an embryo comprising a particular plasmid.

Group XIII, claim(s) 34 and 35, drawn to a method for producing a non-human gene-mutated animal.

Group XIV, claim(s) 43, drawn to a method of diagnosing Alzheimer's disease or a possibility of onset of Alzheimer's disease using a mutant presenilin-1 gene.

Group XV, claim(s) 44 and 45, drawn to a substance for treating Alzheimer's disease.

Group XVI, claim(s) 46-50, drawn to a hybrid gene mutant animal comprising a mutant presenilin-1 gene and mutant beta amyloid precursor protein.

4. It is noted that although claims 3 and 4 have been put in group II, the animals recited in these claims lack the same special technical feature because they all would comprise a particular mutant presenilin-1 gene, each mutant gene comprising mutation of a particular amino acid or a combination of more than one amino acid. Since the structure and function of a protein is dependent on its primary structure and change of even one amino acid would change the three dimensional structure of the protein, each mutant protein would produce a distinct transgenic non-human animal that would have different genotype, phenotype and characteristics and therefore would have different utilities. In summary, the multiplicity of the animals encompassed by this group would not have the same special technical feature. Therefore, in the event group II is elected for prosecution, Applicants are required to elect an animal with one mutation or one combination of mutations for further prosecution and that non-elected inventions will be withdrawn from further consideration.

The invention of group I lacks the same technical feature as those of the groups II-V and XVI because they comprise different transgenes with different mutations in the transgene. Additionally, the characteristics of the animals of one group would be different from those of the other group. It is noted that a mutant presenilin-1 gene could comprise any mutant, however, one mutant would lack the same technical feature as the other one because two different mutations may affect a protein function differently. It is well known in the prior art that alteration of one single amino acid would alter the function of a protein. The invention of group I also lacks the same technical feature as those of the groups VI-XV because the nucleic acid of these groups

The inventions of the groups VI-X lack the same technical feature because they are drawn to different DNA molecules with different nucleotide sequences and sequence elements.

The inventions of the groups XI and XII lack the same technical feature because they comprise different DNA sequences.

The methods of groups XIII and XIV lack the same technical feature because they are drawn to methods that have different steps and would result in different products.

The compounds of group XV lack the same technical feature as that of group I because a compound isolated by using the methods of claims 44 or 45 could be isolated by any other transgenic animal models of Alzheimer's disease.

5. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art shown by their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

When amending claims, applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to § 1.121(c). For instructions, Applicants are referred to http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm.

Applicants are also requested to submit a copy of all the pending/under consideration claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are

unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (703) 305-3388.

Ram R. Shukla, Ph.D.

RAM R. SHUKLA, PH.D
PATENT EXAMINER